Catalyst Biosciences Receives FDA Fast Track Designation for Subcutaneous MarzAA for the Treatment of Episodic Bleeding in Factor VII Deficiency

June 28, 2021

Second Fast Track Designation for MarzAA

SOUTH SAN FRANCISCO, Calif., June 28, 2021 (GLOBE NEWSWIRE) -- Catalyst Biosciences, Inc. (NASDAQ: CBIO) today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for Marzeptacog alfa (activated), MarzAA, the Company's subcutaneously (SQ) administered next-generation engineered coagulation Factor VIIa (FVIIa) for the treatment of episodic bleeding in subjects with Factor VII deficiency. Catalyst is currently enrolling patients with FVII deficiency in a Phase 1/2 open-label study. This trial is being conducted in parallel with the ongoing Phase 3 registration trial evaluating MarzAA for the treatment of episodic bleeds in patients with Hemophilia A or B with inhibitors.

Fast Track is an FDA process designed to facilitate and expedite the development and review of drug candidates that have demonstrated the potential to address an unmet medical need in treating serious diseases or conditions. A drug candidate with Fast Track designation is eligible for greater access to the FDA as well as a priority review and rolling review of the marketing application.

"Receiving a second Fast Track designation is another important milestone in our MarzAA development program. We look forward to our continued collaboration with the FDA to bring a safe and effective treatment to patients with Factor VII deficiency, Hemophilia A or B with inhibitors, Glanzmann Thrombasthenia and other severe bleeding disorders." said Nassim Usman, Ph.D., president and chief executive officer of Catalyst. "MarzAA is the only subcutaneously administered bypassing agent under development for the episodic treatment of bleeding events and has the potential to significantly improve the lives of patients with several inherited or acquired bleeding disorders."

FDA granted Fast Track Designation for MarzAA for the SQ treatment and control of episodic bleeding in subjects with Hemophilia A or B with inhibitors in December 2020.

About Catalyst Biosciences, the Protease Medicines company
Catalyst is a research and clinical development biopharmaceutical company focused on addressing unmet medical needs in rare disorders of the complement and coagulation systems. Our protease engineering platform has generated two late-stage clinical programs, including MarzAA, an SQ administered next-generation engineered rFVIIa for the episodic treatment of bleeding in subjects with rare bleeding disorders. Our complement pipeline includes a preclinical C3-degrader program licensed to Biogen for dry age-related macular degeneration, an improved complement factor I protease for SQ replacement therapy in patients with CFI deficiency, and C4b-degraders designed to target disorders of the classical complement pathway, as well as other complement programs in discovery.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the potential for MarzAA to treat and control episodic bleeding in subjects with Factor VII deficiency, Hemophilia A or B with inhibitors, Glanzmann Thrombasthenia and other severe bleeding disorders, the benefits of Fast Track designation, and the benefits and uses of MarzAA and Catalyst's other product candidates. Actual results or events could differ materially from the plans, intentions, expectations, and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially, including, but not limited to, the risk that the one or both of the clinical trials of MarzAA may be delayed or terminated as a result of COVID-19, competitive products and other factors, that trials may not have satisfactory outcomes, that additional human trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of MarzAA, including the generation of neutralizing antibodies, the risk that Fast Track designation will not lead to a faster or less costly product approval process, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, including as a result of delays in trial enrollment, development and manufacturing resulting from COVID-19 and other factors, competition and other risks described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 6, 2021, and in other filings with the Securities and Exchange Commission. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

Contact:

Ana Kapor
Catalyst Biosciences, Inc.
investors@catbio.com

Source: Catalyst Biosciences, Inc.